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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

D1296 B

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 27 1997

WARNING LETTER

Kenneth K. York, M.D.
210 South Grand Avenue
Suite 215
Glendora, California 91741

Dear Dr. York:

This letter is in response to the January 13, 1997, certification you submitted to demonstrate that the Summit Technology Omnimed excimer laser, Serial Number 5091, is identical in all relevant aspects to lasers approved by the Food and Drug Administration.

We regret to inform you that your certification is incomplete, and therefore inadequate, as submitted. Your certification states that "the computer hardware, firmware, and software in my laser allow it to perform all the procedures of the PMA approved device in an identical manner." A certification must establish that the limitations of operation required under the approved premarket approval (PMA) apply to your laser. Your submission does not adequately address the restrictions required under the PMA relating to the clinical capabilities of the laser; you have not stated that your device is enabled only for those indications and conditions for which the model received PMA approval.

Furthermore, a December 8, 1995, letter from Mr. William Appler, who was then representing you, indicated that you had modified the delivery system for your laser. You also indicate in your certification that your laser has a unique detachable unit which you have developed to treat your patients. This modification appears to contradict your statement that this laser performs all the procedures of the PMA approved device in an identical manner.

Because you modified your laser, you are considered to be a manufacturer under Title 21 of the Code of Federal Regulations (CFR) 1040.10(i) and are subject to the Federal Performance Standard for lasers. Submission of a Laser Product Report is required under 21 CFR 1002.10. To date, we have not received such a report.

We have repeatedly informed you (in the April 26, 1995, letter we sent you, as well as an April 8, 1995, Warning Letter to Hi-Line Medical, who acted as the importer for your laser, and additional correspondence between your counsel and the FDA on August 1, 1995, November 8, 1995, and April 8, 1996) that your excimer laser is a Class III device that is subject to the provisions of the Federal Food, Drug and Cosmetic Act (the Act). Your laser is required to have in effect either an approved premarket approval application (PMA) or an investigational device exemption (IDE).

Your laser is not a custom device and is not exempt from the requirement under the Act that the device have a PMA in effect. Section 520(b) of the Act establishes four conditions, each of which must be met in order for a device to be a custom device. Among these conditions is that the device be made to meet either the specific anatomical requirements of an individual patient or the special needs of an individual practitioner; a practitioner's special needs may be either an individual anatomical need or a special practice need that is not shared by the physician's fellow specialists. There is no evidence that your device has been designed to meet any special anatomical needs that you or a particular patient of yours may have. In addition, your device is not intended to meet a special practice need, because the requirements of your medical practice are not unique in that they are shared by numerous other health professionals of the same specialty.

Please notify us within 15 days of your receipt of this letter as to what, if any, actions you are taking or plan to take to bring your device into compliance. A copy of the guidance document prepared by the Office of Device Evaluation for submitting an IDE for an ophthalmic excimer laser is enclosed. Continued use of your device before you receive an approved IDE and submit a Laser Product Report may result in regulatory action by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Your response should be sent to the attention of Mary-Lou Davis, Dental, ENT and Ophthalmic Devices Branch (HFZ-331) at the letterhead address. In addition, please send a copy of your response to Dannie Rowland, Compliance Officer, Food and Drug Administration, 19900 MacArthur Blvd., Suite 300, Irvine California 92715-2445. If you have further questions, please contact Mary-Lou Davis at (301)594-4613, ext. 127 or FAX: (301) 594-4638.

Sincerely yours,

Lillian J. Gill

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health